

REMARKS

Reconsideration of the above-identified application is respectfully requested. Claims 15 – 18 and 21 are presently pending in this application subsequent to the above amendments. Claims 1-14 and 19-20 have been cancelled without prejudice to their prosecution in a subsequent application. Claim 15 has been amended to incorporate the subject matter of its dependent claim 20, and claim 21 has been amended to correct its dependency since claim 19 is no longer pending. Support for the amendments can be found in the claims as filed since the amendments do not alter the scope or content of the claims in any manner. Thus, no new matter has been added.

REJECTION UNDER 35 USC § 112, SECOND PARAGRAPH

The Examiner has rejected claims 19 to 21 under the second paragraph of 35 USC § 112 on the asserted basis that the recitation "a weight average molecular weight" is unclear.

Applicants respectfully traverse. It is submitted that the term "a weight average molecular weight" is routinely used in the field of polymer science to distinguish from number average molecular weight when describing the molecular weight of polymers. It is generally known that a polymer sample usually has a distribution of molecular weights as some of the polymer chains in the sample will be larger and others smaller. Accordingly, one of skill in the art would readily understand the term and its use in the claims. Thus, claims 19 to 21 would be clear and precise to one possessing an ordinary level of skill in the pertinent art. Applicants respectfully request that the Patent Office withdraw the objection.

REJECTIONS UNDER 35 USC § 102(b)

The Examiner has rejected claims 15 to 16 and 19 under 35 USC § 102(b) as assertedly anticipated by Fujikawa ("Sulphated Polysaccharide of the Thallus of Brown Seaweed *Undaria pinnatifida*") and claims 15 and 16 as assertedly anticipated by Funahashi et al. (JP2002-20403).

The Fujikawa document describes the isolation of sulfated polysaccharides from Wakame and the isolation of a fucogalactan sulfate with a molecular weight of approximately 200,000. The Examiner acknowledges that Fujikawa does not disclose using the isolated fucogalactan sulfate in a composition for the treatment, control or prophylaxis of a viral infection. It is respectfully submitted that in view of the claim amendments to recite that the galactofucan sulfate has a weight average molecular weight of greater than about 500,000 Daltons, the objection is obviated and Applicants respectfully submit that it should be withdrawn.

Turning to claims 15 and 16, Funahashi, *et al.*, teaches the isolation of an apoptosis inducing polysaccharide from Wakame. The citation discloses that a polysaccharide fraction with a mw ranging from 50,000 to 100,000 is associated with apoptosis induction factors and may be useful for cancer treatment. In view of the claim amendments, it is submitted that the objection is obviated and Applicants respectfully submit that it should be withdrawn.

REJECTIONS UNDER 35 USC § 103

The Examiner rejected claims 15 and 17 to 21 as assertedly obvious in view of Funahashi *et al.* It is asserted that although the reference does not teach using sporophyll material itself in combination with additional polysaccharide, a person of skill in the art would reasonably expect that crude sporophyll would contain the same anti-viral properties as the purified polysaccharide.

Applicants respectfully traverse. Firstly, Applicants note that the citation does not teach the extraction of a galactofucan sulfate from leaves of Wakame. Rather the citation discusses extracting polysaccharides from the sporophyll material (mekabu) of the plant. Applicant respectfully submits that the leaves of Wakame are quite distinct from the sporophyll material. Further, there is nothing in the citation to suggest that combining crude sporophyll material with galactofucan sulfate isolated from leaves would produce a product with superior properties. The citation provides neither directions nor motivation to dilute the active ingredient with crude plant material. In contrast, Figure 1 of the citation illustrates that the purification of a 50,000 to 100,000 molecular weight fraction resulted in superior activity.

Thus, the citation teaches that the apoptosis inducing ability of the active component is enhanced when isolated. Accordingly, the skilled person would expect that the crude material would have inferior properties. Indeed, a person of ordinary skill in the art would consider that the many other compounds present in crude sporophyll material could inhibit or reduce the effectiveness of the isolated active ingredient if the two materials were combined. Accordingly, there is nothing in the citation to motivate a person of ordinary skill to combine sporophyll material and the galactofucan sulfate extract as claimed.

The Office Action also contends that it would be obvious in light of Funahashi *et al.*, for a skilled person to routinely optimise the amount of the active agent to arrive at the amount of galactofucan sulfate in the composition as set out in claim 18.

Applicants respectfully traverse. As it is not obvious to combine the purified polysaccharide from leaf with sporophyll material in the first place, then calculating the amount of polysaccharide to use in the composition would also not be obvious. Further, working with crude sporophyll material and a purified extract in a single composition would create complications and difficulties in assessing the useful amount of each component in the composition. Thus, as the combining of sporophyll material and polysaccharide to provide a useful composition is a surprising result, it follows that determining the parameters for obtaining such a composition can not be considered obvious.

The Examiner also contends that it would also be obvious in light of Funahashi *et al.*, to select the different molecular weight fractions of galactofucan sulfate as set out in claims 19 to 21. However, the Funahashi citation specifically teaches that the preferred molecular weight range is 50,000 to 100,000 and demonstrates that this fraction has superior apoptosis activity to other fractions. Again, Applicant respectfully refers to Figure 1 of 15 Funahashi *et al.*, which demonstrates that the 50,000 to 100,000 mw fraction has enhanced activity and is more effective at inducing apoptosis than other fractions. Thus, Funahashi *et al.*, teach away from isolating larger molecular weight fractions to obtain greater activity. Further, a person of ordinary skill in the art would be aware that it is generally considered that larger molecular weight compositions and compounds are likely to

have low bioavailability and hence poor activity *in vivo*. Therefore, as the disclosure of the cited document teaches away from isolating larger molecular weight fractions, there are no directions to isolate higher molecular weight polysaccharide fractions. In the absence of any such directions there can be no motivation for a person of skill to obtain larger molecular weight fractions to achieve better effects. Accordingly, Applicant respectfully requests that the objection be withdrawn.

The Examiner has also rejected claims 15 and 19 to 21 on the basis that they are obvious in light of the teachings of Fujikawa. It is contended that it would be obvious to modify the polysaccharide of Fujikawa to produce polysaccharides of different molecular weights.

Applicants respectfully traverse. Fujikawa only describes the isolation of two major fractions of polysaccharides. There is nothing in the citation that would suggest that further modifications of the Fujikawa method would produce different molecular weight species. Further there is no teaching or suggestion as to which parameters must be varied or how to vary the parameters to obtain higher molecular weight fractions. The prior art gives no indication as to which parameters are critical and gives no direction as to which conditions would be successful. Thus, in the absence of such direction there can be no motivation for the skilled person to modify the extraction procedures of Fujikawa. There is also nothing in the document that would motivate the skilled person to try and isolate higher molecular weight species. As discussed above, a person of ordinary skill would also not be motivated to try and produce larger molecular weight fractions of the polysaccharides as larger molecular weight fractions compounds have typically lower bioavailability than compounds of lower molecular weights. Therefore, it is respectfully submitted that the present claims could not be considered obvious in light of the citation.

For the foregoing reasons, Applicants respectfully submit that the claims are in compliance with 35 U.S.C. § 101 *et. seq.* Accordingly, Applicants respectfully request allowance of all pending claims. Applicants have made a good faith effort to place this application in condition for allowance. However, should the Examiner have any further questions about the application, Applicants respectfully request the Examiner to contact the undersigned attorney at (425) 455-5575 to resolve the

matter. If any need for any fee is found, for any reason or at any point during the prosecution of this application, kindly consider this a petition therefore and charge any necessary fees to Deposit Account 07-1897.

DATED May 19, 2005

Respectfully submitted,

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Enclosures:

Petition for One Month Extension of Time
Check No. 23977 for \$60.00
Postcard